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The mother of invention—introduction of a novel inflatable stent for McIndoe neovagina

2020 has surely been the Year of the Coronavirus—a year of disruption, heartache, and challenges in both health care and at home. Despite the clear and unwelcome adversity of the past 12 months, the pandemic has also ushered in an era of tremendous opportunities for growth and creativity. COVID-19 has fostered numerous innovations in health care as we have acted rapidly to work around interrupted supply chains, staffing shortages, overwhelmed hospitals, and limited inventory. With the possibility of a post-COVID world now tantalizingly close, we can picture a landscape of ample COVID-19 vaccinations, improved availability of hospital beds, and an influx of elective surgeries for patients whose procedures had been delayed or cancelled due to the vagaries of the pandemic. One such elective gynecologic surgery is the McIndoe vaginoplasty, a classic surgical approach for neovagina creation. The inflatable vaginal stent devised and described by Romanski et al. in their video article (1) is a prime example of the kind of originality and innovation that is possible when devices are discontinued, are unavailable, or are in limited supply. Although COVID-19 was not cited as the impetus for the creation of their stent, the authors do reference the discontinuation of a previously used commercial device as the motivation for this novel system.

The goal for creating a neovagina in patients with vaginal agenesis, commonly found in Mayer-Rokitansky-Kuster-Hauser syndrome and complete androgen insensitivity syndrome, is to elongate the vagina not only for functional, penetrative intercourse, but also for cosmesis and psychosexual well-being. The majority of patients with vaginal agenesis can be treated successfully and nonsurgically by means of vaginal dilation. Success rates for vaginal dilation have been reported to be as high as 91.9% with the use of the Ingram method. Of the remaining 8.1% who failed conservative management, all were successfully treated surgically with the use of a McIndoe procedure (2). Therefore, for the subset of patients who fail nonsurgical management or desire a more aggressive option, McIndoe vaginoplasty is an effective approach and can improve quality of life.

McIndoe vaginoplasty is largely a niche surgical procedure that requires a trained surgeon for optimal results. This includes management of possible surgical complications such as breakdown of the skin graft, vaginal coaptation, infection, and fistulization. Complications such as vaginal stenosis, vaginal shrinkage, granulation tissue formation, transplant defect, bleeding, and infection have been reported in up to 65% of cases, and 33% required additional surgery (3). Therefore, novel ideas to improve technique, increase success, and decrease complications are always welcomed.

As reported in this issue of *Fertility and Sterility*, Romanski et al. have constructed a novel inflatable vaginal stent for McIndoe vaginoplasty and published an easy step-by-step video guide for clinicians. They highlight the ease of recreating a relatively inexpensive stent in less than 10 minutes with only nine standard operating room supplies that otherwise meets all the other requisites: radiopacity, open drainage point, and evenly distributed, yet soft circumferential compression to avoid pressure necrosis of the vagina and damage to the bowel or bladder. Once placed, the stent would remain in situ for 7 days after surgery before reverting to standard vaginal dilation to maintain vaginal length and patency. The authors' thoughtful design displays their surgical expertise in McIndoe vaginoplasty as well as their desire to advance surgical practices in reproductive medicine. We commend them on their important and useful work.

Historically, various vaginal stents have been trialed to keep the skin graft in place, including rigid stents made of wood or Pyrex glass, and soft stents, such as sterile condom molds with gauze, surgical foams, or silicone. The concept of this inflatable vagina stent is not truly "novel," but rather an updated rendition of previous versions of condom molds (4), as well as a replacement for a stent that is no longer commercially available. Because sterile condom molds are not always available or allowed to be retained in patients after surgery, the authors' objective is rather to use inexpensive readily available presterilized supplies that meet operating room guidelines and may be retained in a patient. This is especially important during the current COVID-19 pandemic.

Because of the variability in its construction, the authors report the advantage of tailoring the vaginal mold to each patient. Although a trained surgeon constructs this stent, there may be variability in outcomes based on adequate construction. For example, to compress the vaginal stent as described by the authors, the surgeon has to manually occlude the stent tightly with their fingers, which may make it difficult for placement of the graft. Slippage may cause torsion or avulsion of the graft, compromising the graft take. Therefore, careful application using a two-person operation is required.

In addition, this stent does not come in different standard lengths and sizes compared with other available soft and rigid molds. Although the authors state that the variability allows surgeons to construct a mold tailored to the patient, this may introduce operator variability, error, and/or dissatisfaction that standardization tends to avoid. Even with a successful surgery, a widened introitus or vagina may decrease patient satisfaction and can be difficult to treat ex post facto. Ideally in surgery and medicine, standardization is preferred, especially with the introduction of a new or updated device.

Although this inflatable stent was specifically characterized for patients undergoing McIndoe vaginoplasty, it stent may be applicable in a broader context, such as the creation of neovagina after pelvic exoneration, irradiation, or penile inversion. It could also be considered in patients undergoing uterus transplantation to avoid stricture at the vaginal anastomoses site that has been noted to commonly occur after transplantation. A patent vaginal canal after a uterus transplantation is important for egress of menstrual flow, cervical biopsies, and embryo transfers (5). Therefore, this vaginal stent has multiple possible implementations, both classic and novel. As the mother of invention, necessity has proven to be highly useful for this team and for the broader audience of

skilled surgeons with expertise in the area of neovagina creation who may benefit from the implementation of this stent.

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